

In the Claims

Applicant has submitted a new complete claim set showing marked up claims with insertions indicated by underlining and deletions indicated by strikeouts.

Please amend pending claim 4 as noted below.

Please add new claim 42 as noted below.

1-3. (Cancelled)

4. (Currently amended) A method for determining regression, progression or onset of a diabetic condition characterized by abnormal levels of glycated protein comprising;

obtaining a level of the amount of K41-glycated CD59 from a sample obtained from a human subject, and

comparing the level to a control as a determination of regression, progression or onset of the condition, wherein the level is obtained using an antibody or antigen-binding fragment thereof that specifically binds K41-glycated CD59 or K41-non-glycated CD59, and wherein a higher level of K41-glycated CD59 in the sample compared to the control indicates onset or progression of the condition and a lower level of K41-glycated CD59 in the sample compared to the control indicates regression of the condition.

5-8. (Cancelled)

9. (Previously presented) The method of claim 4, wherein the sample is a fluid sample.

10. (Previously presented) The method of claim 9, wherein the fluid sample is blood.

11. (Previously presented) The method of claim 9, wherein the fluid sample is urine.

12. (Previously presented) The method of claim 4, wherein the subject is diabetic.

13. (Previously presented) The method of claim 4, wherein the subject is free of symptoms calling for a therapy with a sugar-regulating therapy.

14. (Previously presented) The method of claim 4, wherein the subject is undergoing therapy for regulating blood sugar levels.

15. (Previously presented) The method of claim 14, wherein the therapy is a non-drug therapy.

16. (Previously presented) The method of claim 14, wherein the therapy is a drug therapy.

17. (Previously presented) The method of claim 16, wherein the drug therapy is an oral blood sugar regulating agent therapy.

18. (Previously presented) The method of claim 16, wherein the drug therapy is an injectable drug therapy.

19. (Previously presented) The method of claim 16, wherein the drug therapy is insulin therapy or an insulin analog therapy.

20. (Previously presented) The method of claim 4, wherein the subject is at increased risk of becoming diabetic.

21. (Previously presented) The method of claim 4, wherein the control level is the level in apparently healthy normal individuals.

22. (Previously presented) The method of claim 4, wherein the control level is a predetermined value.

23. (Previously presented) The method of claim 4, wherein the control level is a level determined for the subject from a sample obtained from the subject at a time separated from the first sample.

24. (Previously presented) The method of claim 23, wherein the time is at least one day.

25. (Previously presented) The method of claim 4, wherein the subject has received treatment for regulating blood sugar levels.

26. (Previously presented) The method of claim 4, wherein the subject has not received treatment for regulating blood sugar levels.

27. (Previously presented) The method of claim 4, wherein the condition is an abnormal blood sugar level.

28. (Previously presented) The method of claim 4, wherein the level is obtained using an immunoassay.

29. (Previously presented) The method of claim 4, wherein the level is measured as a percentage of the total CD59 in the sample.

30. (Previously presented) The method of claim 4, wherein the level is the level of K41-glycated CD59 relative to the level of K41-nonglycated CD59 in the sample.

31. (Previously presented) The method of claim 4, wherein the antibody or antigen-binding fragment thereof binds specifically to K41-glycated CD59.

32. (Previously presented) The method of claim 4, wherein the antibody or antigen-binding fragment thereof is detectably labeled.

33. (Cancelled)

34. (Previously presented) The method of claim 4, wherein the antibody is a monoclonal antibody.

35. (Previously presented) The method of claim 4, wherein the antibody is a polyclonal antibody.

36. (Previously presented) The method of claim 4, wherein the level is obtained using two antibodies or antigen-binding fragments thereof, a first antibody or antigen-binding fragment thereof that binds both glycated and nonglycated CD59 and a second antibody or antigen-binding fragment thereof that binds only one of a glycated K41 of CD59 and a nonglycated K41 of CD59.

37. (Previously presented) The method of claim 36, wherein one or more of the first and second antibody or antigen-binding fragment thereof is detectably labeled.

38. (Cancelled)

39. (Previously presented) The method of claim 36, wherein one or more of the first and second antibodies is a monoclonal antibody.

40. (Previously presented) The method of claim 36, wherein one or more of the first and second antibodies is a polyclonal antibody.

41. (Previously presented) The method of claim 4, wherein the sample is a tissue sample.

42. (New) The method of claim 4, wherein the sample is a saliva sample.